



Certificate of Analysis

Productname: Citronellae etheroleum

Inspection No: J10635/0223/536

Batchnumber: 22K09-T12-100070

Expiration date: 31.10.2025

Analysed according to: ČL 2017, Ph.Eur.10.0

Original Manuf. Date: 1.11.2022

Sample Unit: 1 x 1 ml

Batch Size: 330 x 250 ml

Identification of producer: V00201

Batch no. of vendor: 1331720

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Light yellow or brownish yellow liquid.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,881 - 0,895	0,890			Fagron CZ
Refractive index	1,463 - 1,475	1,469			Fagron CZ
Optical rotation	-4 - +1,5	-3,4	°		Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
limonene	1,0 - 5,0	4,2	%		Contract Lab
citronellal	30,0 - 45,0	34,9	%		Contract Lab
citronellyl-acetate	2,0 - 4,0	2,6	%		Contract Lab
neral	<=2,0	0,2	%		Contract Lab
geranial	<=2,0	0,4	%	Geranial	Contract Lab
geranyl-acetate	3,0 - 8,0	3,2	%		Contract Lab
citronellol	9,0 - 15,0	12,5	%		Contract Lab
geraniol	20,0 - 25,0	21,5	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Quality: Excipient

Performed by: Pavla Šlězarová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 12.12.2022

Conclusion: **APPROVED**

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